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September 10, 2001

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FSIS Docket Clerk
Docket No. 97-013 P
Food Safety and Inspection Service
United States Department of Agriculture
Room 102, Cotton Annex Building
300 12th Street, S.W.
Washington, D.C. 20250-3700

97-013P-2721
97-013P
Joe Harris

Re: Performance Standards for the Production of Processed Meat and Poultry Products

The Southwest Meat Association (SMA) respectfully submits these comments in response to the Food Safety and Inspection Service's (FSIS) Proposed Rule on performance standards for the production of ready-to-eat meat and poultry products. SMA is a regional association representing mostly small to medium sized meat and poultry processors in the southwestern U.S. Most of our members produce some forms of ready-to-eat products.

In general, we support the agency's move away from "command and control" toward a more performance based system of inspection. The agency has publicly announced its intentions to become a "regulatory public health agency" that used science-based policies to regulate the industry. The current proposal, we feel, does not accomplish this goal of having regulations based upon sound science. As an industry committed in the strongest possible way to producing safe and wholesome foods, we are also committed to basing food safety programs on the best available science. This, we feel, is the only way by which to achieve our common food safety goals.

Proposed Lethality Performance Standards

We generally are in support of the agency's proposed lethality performance standards. The proposed standard is based on achieving probabilities of no greater than a certain level of surviving *Salmonella* per 100 grams of product or on achieving a certain log reduction of *Salmonella* throughout the finished product. While most small firms would be hard-pressed to develop individualized lethality treatments to achieve the standards, the compliance guide, as a safe harbor, is useful in this regard. Relative to validating lethality

treatments, we think the agency must provide specific details about acceptable protocols for conducting these validation studies (i.e., numbers of samples, types of data, specific conditions, etc.). In the past, this has been a very contentious issue between the agency and the industry. Thus, we strongly urge the agency to clearly specify what is required in validation studies, thereby minimizing the amount of interpretation of data by FSIS personnel.

Draft Compliance Guidelines

While SMA appreciates the development of the compliance guidelines as practical "safe harbors" for achieving the performance standards, the current draft guidelines fall far short of being providing sufficient guidance. One example is the beef jerky example described in the compliance guidelines for destroying *E. coli* O157:H7. While the guideline provided for achieving the performance standard likely is effective, the process itself does not resemble commercial jerky production. Also, it would be much more useful for processors if the pertinent data, studies, literature, etc. used to develop the guidelines were included. This would make it much easier for processors to ensure that the processing conditions upon which the guidance materials were based actually match the establishments' conditions.

Proposed Stabilization Performance Standards

The SMA is very strongly opposed to the proposed stabilization performance standards. Instead of broadly expanding current stabilization performance standard to include all heat-treated and ready-to-eat products, FSIS should base new performance standards on risk. To date, the agency has not provided any data to indicate that such an expansion would have a positive impact on public health, nor has the agency even provided data to indicate that there have been foodborne illness outbreaks linked to products having been improperly chilled at the processing plant. We are unaware of even a single *Clostridium perfringens* illness having been traced to a cooling defect in a state or federally inspected facility.

The agency's baseline data that were used to develop the performance standard of no more than one log growth of *C. perfringens* during cooling appear to dramatically overestimate the actual hazard present. First, the agency assumed that all vegetative *C. perfringens* cells present in raw meat and poultry would form spores that would survive cooking and that, subsequently, all of these spores could germinate after lethality treatment. Further, industry data presented at the May 9th public meeting indicate the actual starting levels of *C. perfringens* are much lower than the 10^4 estimated by the agency. Industry personnel speaking at the public meeting presented data from 53 lots of product that had not met the existing stabilization performance standard. The product from these lots was tested for levels of *C. perfringens*. A total of 340 samples were tested with the following results: 336 samples undetectable *C. perfringens*; 2 samples 11-100/g; and 2 samples 110-140/g. Also not considered by the agency when developing the proposal were the studies showing that *C. perfringens* die during refrigeration. There is a 1-log reduction after only 24 hours of refrigerated storage. Finally, the agency failed to

consider the impact of product formulation on the germination and growth rates of *C. perfringens*.

We believe it is incumbent upon FSIS to base new regulations upon risk and the best available science. The proposed stabilization performance standard fails in this regard.

Proposed Mandatory *Listeria* Testing

The SMA is strongly opposed to the proposed mandatory *Listeria* testing for establishments producing ready-to-eat (RTE) products. The proposed testing will not advance the public health goals stated by the agency and shared by our industry. The meat and poultry industries have been very aggressive in taking steps to reduce the incidence of *Listeria* in RTE products and in processing facilities. The SMA, along with several other industry associations, developed and widely disseminated a joint set of *Listeria* control guidelines for use by processors. The agency has proposed a "one-size-fits-all" approach to the mandatory testing, while its own draft risk assessment (in conjunction with the Food and Drug Administration) clearly recognizes that not all RTE products pose the same degree of risk.

The proposed rule, although it bases the number of samples to be tested on production volume, will be disproportionately burdensome on small processors. The proposal requires sampling each production "line," but provides no definition of what constitutes a line. Many small processors produce a very large variety of products, each in relatively small volumes. Requirements for testing each "line" could be beyond burdensome and even force some processors out of business. Furthermore, the agency failed to even speculate, much less provide data, on the anticipated reduction in foodborne listeriosis if the proposed rule is enacted. Again, if the agency is to become a true regulatory public health agency, it must consider the potential public health benefit -- or lack thereof -- of its regulations.

Conclusion

We appreciate the opportunity to comment on this extremely important proposal, and we share the agency's objective of reducing the incidence of foodborne illness linked to federally inspected meat and poultry products. We urge the agency in the strongest possible terms to provide sound scientific justification for new rules or regulations, and we look forward to working cooperatively with FSIS to achieve this goal.

Respectfully submitted,

Joe Harris

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